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## *Drug Device and Biotech*

### In This Issue

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## **FDA Supports Preemption of State Law Failure to Warn Claims in Pharmaceutical Liability Actions<sup>1</sup>**

*By Melissa M. Thornton and Quentin Urquhart*

### **Introduction**

On January 18, 2006, the FDA promulgated a final rule modifying prescription drug label regulations for the first time in twenty-five years. The rule primarily revises the format of the package insert to “enhance the safe and effective use of prescription drug products and reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information.”<sup>2</sup> The most significant changes to the label include the addition of an introductory “Highlights” section containing a concise summary of the prescribing information, a table of contents, minimum graphical requirements, and a toll-free number and Internet reporting information for suspected adverse events.<sup>3</sup> However, the FDA also used the revision as an opportunity to formally state its view that FDA approval of prescription drug labeling under the Federal Food, Drug, and Cosmetic Act (“FDCA”) preempts certain state law product liability claims.<sup>4</sup> Although the FDA has recently advocated for preemption of state law claims as *amicus curiae* in several product liability suits,<sup>5</sup> the Preamble to the new rule contains the first legislative policy statement by the FDA that federal drug labeling requirements preempt state law failure to warn claims.

### **Background**

#### **The Doctrine of Preemption**

The Supremacy Clause, Article VI, clause 2, of the United States Constitution preempts state laws that “interfere with, or are

contrary to” the exercise of federal power.<sup>6</sup> In all preemption cases, “[t]he purpose of Congress is the ultimate touchstone.”<sup>7</sup> Federal preemption may be express or implied, and occurs whether Congress’ intent is “explicitly stated in the statute’s language or implicitly contained in its structure and purpose.”<sup>8</sup> Moreover, federal regulations compel preemption to the same extent as federal statutes so long as they are not unreasonable, unauthorized, or inconsistent with the laws under which they are promulgated.<sup>9</sup>

Federal preemption of state law falls into three general categories:

- **Express Preemption** The strongest form of preemption, express preemption occurs when Congress includes explicit preemptive language in a piece of legislation.<sup>10</sup>
- **Field Preemption** In the absence of explicit preemptive language, Congress’ intent that federal law precludes state action may be inferred when federal legislation occupies an entire field, leaving “no room for the States to supplement it,” or when the federal interest is “so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.”<sup>11</sup>
- **Conflict Preemption** State law is also invalidated when it directly conflicts with a federal regulation.<sup>12</sup> Thus, conflict preemption occurs either when “compliance with both federal and state law is a physical impossibility” or when state law “stands as an obstacle to the full purpose and objectives of Congress.”<sup>13</sup>

### Preemption by the FDCA

Many courts have already found that certain state law claims common to product liability suits are preempted by the Food, Drug, and Cosmetic Act:

- **Fraud-on-the-FDA** In *Buckman Co. v. Plaintiffs’ Legal Committee*, the Supreme Court held that state law fraud-on-the-FDA claims conflict with, and therefore are impliedly preempted by, federal law.<sup>14</sup> The Court determined that “the conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration.”<sup>15</sup> The Court found that allowing the state law actions would cause manufacturers “to fear that their disclosures to the FDA, although deemed appropriate by the Administration, would be later judged insufficient in state court.”<sup>16</sup> As a result, manufacturers “would have an incentive to submit a deluge of information that the Administration neither wants or needs.”<sup>17</sup> Thus, the Court reasoned that requiring manufacturers to comply with both the FDA’s detailed regulatory scheme and the tort regimes of the 50 states would burden both manufacturers and the FDA alike.<sup>18</sup>
- **Medical Devices** The Medical Device Amendments to the FDCA contain an express preemption clause invalidating any state law requirement relating to safety or effectiveness which is “different from, or in addition to” existing federal regulations.<sup>19</sup> Relying upon this provision, a number of medical device manufacturers have successfully argued in favor of preemption of state law product liability claims including failure to warn and defective design.<sup>20</sup>
- **Pharmaceutical Drugs** The portion of the FDCA that is applicable to prescription drugs does not contain an express preemption provision. Nevertheless, pharmaceutical manufacturers have argued that state law failure to warn claims are impliedly preempted because they conflict with labeling regulations promulgated by the FDA. Most courts have rejected this argument on at least one of two grounds.<sup>21</sup> First, these courts point

to the FDA's 1965 amendments to the labeling regulations, which expressly permit manufacturers "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction" without prior approval by the FDA, as evidence that state and federal requirements are complementary.<sup>22</sup> Secondly, these courts reason that FDA regulations are merely minimum safety standards which may be supplemented or strengthened by state law.<sup>23</sup>

### **The FDA's Position on Preemption**

The FDA's position regarding preemption of state law failure to warn claims appears in the Preamble to the final rule. In response to concerns expressed by manufacturers that the proposed labeling changes would make manufacturers more vulnerable to state law failure to warn claims, the FDA concluded that many such claims conflict with FDA approval of labeling under the FDCA, and therefore are impliedly preempted.<sup>24</sup> In support of its position, the FDA set forth "the government's long standing views on preemption," focusing particularly on state laws requiring labeling that "conflicts with or is contrary to FDA-approved labeling."<sup>25</sup>

First, the FDA articulated its role under the FDCA as "the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risk and benefits of the product and is truthful and not misleading."<sup>26</sup> The FDA went on to highlight the importance of prescription drug labeling and the FDA's involvement in the labeling approval process:

The centerpiece of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to

health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. The FDA carefully controls the content of labeling for a prescription drug, because such labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use. FDA continuously works to evaluate the latest available scientific information to monitor the safety of products and to incorporate information into the product's labeling when appropriate.<sup>27</sup>

According to the FDA, "[s]tate law actions can rely on and propagate interpretations of the [FDCA] and FDA regulations that conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory mandate."<sup>28</sup> Specifically, the FDA took issue with the courts' rejection of preemption on the ground that FDA labeling regulations allow manufacturers wide latitude to add or strengthen warning statements without first obtaining permission from the FDA.<sup>29</sup> The FDA went on to clarify that "in practice manufacturers typically consult with the FDA" before adding risk information to the labeling, and thus, "the determination whether labeling revisions are necessary is, in the end, squarely and solely the FDA's under the [FDCA]."<sup>30</sup> The FDA also addressed the view that FDA regulations are merely minimum safety standards which may be supplemented by state law.<sup>31</sup> According to the FDA, the FDCA represents both a "floor" and a "ceiling" for the risk information that should be disclosed by manufacturers.<sup>32</sup> Moreover, "[g]iven the comprehensiveness of FDA regulation...additional requirements for the disclosure of risk information are not necessarily more protective of patients."<sup>33</sup> In fact, the FDA

cautioned against over-warning, stating that additional labeling requirement “erode and disrupt careful and truthful representation of benefits and risks” so essential to prescribers.<sup>34</sup>

The FDA went on to discuss other ways that state law can “undermine safe and effective use” of prescription drugs. First, liability concerns put pressure on manufacturers to include speculative risks in the labeling, thus limiting physician appreciation of more serious side effects and causing meaningful risk information to lose its significance, while simultaneously discouraging use of a drug for an approved use.<sup>35</sup> Also, state law actions threaten the FDA’s role as the agency responsible for evaluating and regulating drugs by requiring “lay judges and juries to second-guess the assessment of benefits versus risk of a specific drug to the general public...sometimes on behalf of a single individual or group of individuals.”<sup>36</sup>

The FDA set forth six specific failure to warn claims that it believes are preempted by the federal labeling regulations:

- Claims that a manufacturer “fail[ed] to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling”;
- Claims that a manufacturer failed to include in direct-to-consumer advertising “any information the substance of which appears anywhere in the labeling” where the manufacturer has “used Highlights consistently with FDA draft guidance regarding the ‘brief summary’” in such advertising;
- Claims that a manufacturer “fail[ed] to include contraindications or warnings that are not supported by evidence that meets standards” set forth in the regulations regarding scientific proof of risk (for example, § 201.57(c)(5), requiring that contraindications reflect “[k]nown hazards and not theoretical possibilities”);

- Claims that a manufacturer “fail[ed] to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims [the warning should have been given]” unless the FDA has determined that material information relating to the proposed warning had been withheld from the FDA;
- Claims that a manufacturer “fail[ed] to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising”;
- Claims that a manufacturer “mad[e] statements that FDA approved for inclusion in the drug’s label” unless the FDA has determined that material information relating to the statements had been withheld from the FDA.<sup>37</sup>

The FDA made clear that preemption affects not only claims against manufacturers, but also claims against health care professionals related to failure to warn of risk information beyond that which is included in the label.<sup>38</sup> The FDA recognized, however, that all state law labeling claims would not be preempted. For example, some state law requirements that “parallel FDA requirements” may not be preempted by the federal regulations.<sup>39</sup>

### **Implications for Product Liability Litigation**

The FDA’s formal statement on preemption should strengthen arguments by drug manufacturers that state law failure to warn claims are preempted by federal labeling regulations. Under *Chevron, U.S.A. v. Natural Resources Defense Council, Inc.*, courts are required to give deference to an agency’s reasonable construction of its regulations and implementing legislation where Congress is silent.<sup>40</sup> Also, the Supreme Court has specifically stated that a federal agency’s own determination that state law stands as an obstacle to the agency’s objectives should “make a difference” in

preemption analyses.<sup>41</sup> Because the FDCA is silent on the preemption of state law failure to warn claims relating to prescription drugs, courts should give weight to the FDA's pronouncement that many such claims interfere with its objectives and are thus preempted by the federal regulations.

If pharmaceutical companies can successfully argue for preemption of state law failure to warn claims, the end result could be a drastic reduction in the number of product liability suits filed, and the redirecting of many others to federal court. Moreover, courts finding in favor of preemption should also find that preemption applies in pending as well as future cases, relying on the FDA's statement that "FDA approval of labeling under the [FDCA], whether it be in the old or new format, preempts conflicting or contrary State law."<sup>42</sup>

However, the FDA's statement is not dispositive. Though the FDA's pronouncement may be persuasive, it is not binding on any court. Its strength may be diminished by the fact that it appears in the Preamble to the rule as opposed to the codified rule itself. Also, there is a strong presumption against implied preemption, a presumption which is even stronger when the federal legislation at issues involves areas traditionally occupied by the states (such as public health and safety),<sup>43</sup> and when federal regulation would preempt state tort remedies.<sup>44</sup> Furthermore, many courts have pointed to the express preemption clause in the Medical Device Amendments of the FDCA and the absence of any such clause relating to pharmaceuticals as evidence that Congress does not intend to preempt failure to state law claims relating to prescription drugs.<sup>45</sup>

In addition, the validity of the FDA's statement on preemption has been fiercely debated since its release in January. When the proposed rule was first published for comment in December of 2000, the FDA stated specifically the rule would not preempt state law.<sup>46</sup> As a result, the preemption language appearing in the

final rule came as a surprise to many, including, for example, the National Conference of State Legislatures which has issued a press release accusing the FDA of "attempting a back-door approach to preempt state prescription drug product liability laws despite Congress and the courts' refusal to grant them such power."<sup>47</sup>

Likely, the FDA's statement will have varying impact among the circuits, and the issue will percolate in the lower federal courts for several years until, and if, it is addressed by the Supreme Court. In the interim, regardless of where individual courts fall on the legal issue, the FDA's statement will not go unnoticed. Federal law requires state and federal courts to take judicial notice of the contents of the Federal Register.<sup>48</sup> Thus, at the very least, juries will be permitted to hear FDA's own description of its involvement in the approval of labeling and supplemental warning language.

1. Melissa M. Thornton, with Quentin Urquhart, IRWIN FRITCHIE URQUHART & MOORE LLC, New Orleans, LA
2. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3922 (Jan. 24, 2006).
3. Press release, The Food and Drug Administration, FDA Announces New Prescription Drug Information Format to Improve Patient Safety (Jan. 18, 2006), available at <http://www.fda.gov/bbs/topics/NEWS/2005/NW01272.html>.
4. See 71 Fed. Reg. at 3934.
5. See e.g., Amicus Brief for the United States, *Motus v. Pfizer, Inc.*, Nos. 02-55372, 02-55498, (9th Cir. Sept. 10, 2002); Amicus Brief for the United States, *Kallas v. Pfizer*, No. 02-04CV0998 (D. Utah Sept. 15, 2005).
6. U.S. CONST. art. VI, cl. 2; *Gibbons v. Ogden*, 22 U.S. 1, (1824).
7. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)(quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)).
8. *Jones v. Ruth Packing Co.*, 430 U.S. 519, 525 (1977).
9. *Fid. Fed. Savs. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153-54 (1982).
10. See *id.* at 152-53.
11. *Id.* at 153 (quoting *Rice v. Santa Fe Elevator*

- Corp., 331 U.S. 218, 230 (1947)).
12. *Id.*
  13. *Id.* (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).
  14. 531 U.S. 341, 348 (2001).
  15. *Id.*
  16. *Id.* at 351.
  17. *Id.*
  18. *Id.* at 350-51.
  19. 21 U.S.C. § 360(k)(a) (“no State...may establish or continue in effect with respect to a device intended for human use any requirement...[w]hich is different from, or in addition to, any requirement applicable under this chapter to the device, and...[w]hich relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.”)
  20. *See, e.g., McCullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005); *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005), *cert. denied*, 126 S. Ct. 420 (Oct. 11, 2005); *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001); *Morton v. Centerpulse Orthopedics, Inc.*, No. S032602GEBGGH, 2005 WL 1366494 (E.D. Cal. May 10, 2005).
  21. *See Hurley v. Lederle Labs.*, 863 F.2d 1173, 1176 & 1176 n.2 (5th Cir. 1988)(collecting cases finding against preemption); *See also, e.g., Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 887 (E.D. Tex. 2005); *Eve v. Sandoz Pharmaceutical Corp.*, No. 98-1429, 2002 WL 181972, at \* 3 (S.D. Ind. Jan. 28, 2002); *Caraker v. Sandoz Pharm. Corp.*, 172 F.Supp.2d 1018, 1032 (S.D. Ill. 2001); *Motus v. Pfizer*, 127 F.Supp.2d 1085, 1087 (C.D. Cal. 2000); *In re Tetracycline Cases*, 747 F. Supp. 543, 550 (W.D. Mo. 1989); *Bansemer v. Smith Labs., Inc.*, No. 86-C-1313, 1990 WL 132579, at \* 1 (E.D. Wis. Sept. 12, 1988).
  22. 21 C.F.R. § 314.70(c)(6)(iii)(A); *Cartwright*, 369 F. Supp. 2d at 881; *Eve*, 2002 WL 181972, at \* 3; *Caraker*, 172 F. Supp. 2d at 1033-35; *Motus*, 127 F. Supp. 2d at 1093-94; *Bansemer*, 2005 WL 132579, at \* 4.
  23. *Cartwright*, 369 F. Supp. 2d at 881; *Caraker* 172 F. Supp. 2d at 1033; *Motus*, 127 F. Supp. 2d at 1092; *In re Tetracycline Cases*, 747 F. Supp. at 549.
  24. 71 Fed. Reg. at 3934.
  25. *Id.*
  26. *Id.*
  27. *Id.*
  28. *Id.*
  29. *Id.*
  30. *Id.*
  31. *Id.*
  32. *Id.* at 3935.
  33. *Id.*
  34. *Id.*
  35. *Id.*
  36. *Id.*; *see also id.* at 3969 (“If State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs for which the FDA has already made a series of regulator determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation of drugs would be disrupted.”)
  37. *Id.* at 3935-36. This list is not exhaustive but represents those claims, at a minimum, which are preempted. *Id.* (“Consistent with its court submissions and existing preemption principles, FDA believe that *at least* the following claims would be preempted by its regulation of prescription drug labeling...”)(emphasis added).
  38. *Id.* at 3936.
  39. *Id.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)(holding that state law damages remedy for violations of FDA requirements does not impose additional requirement upon medical device manufacturers but “merely preserves another reason for manufacturers to comply with...federal law.”)); *cf. Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 352-53 (2001)(holding that “fraud on the FDA” claims are preempted by Federal law); *In re Orthopedic Bone Screws Prod. Liability Litig.*, 159 F.3d 817, 824 (3d Cir. 1998)(“Congress has not created an express or implied private cause of action for violations of the FDCA or the MDA [Medical device amendments]”).
  40. 467 U.S. 837, 842-43 (1984).
  41. *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 883-84 (2000).
  42. 71 Fed. Reg. at 3934.
  43. *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1032 (S.D. Ill. 2001).
  44. *Mazur v. Merck & Co., Inc.*, 742 F. Supp. 239, 246 (E.D. Penn. 1990).
  45. *See, e.g., Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 885 (5th Cir. 2005).
  46. Requirements on Content and Format of

- Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81082, 81103 (Dec. 22, 2000).
47. Press release, National Conference of State Legislatures, Proposed FDA Rule Preempts State Product Liability Laws: Back-door approach seeks powers denied by Congress and the courts (Jan. 13, 2006), *available at* <http://www.ncsl.org/programs/press/2006/pr060113.htm>
48. 44 U.S.C. § 1507 (“The contents of the Federal Register shall be judicially noticed....”).